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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,202	08/10/2005	F. C. Thomas Allnutt	08717.0007	8629
22852 7590 07/10/2007 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EXAMINER EPPS FORD, JANET L	
			ART UNIT 1633	PAPER NUMBER
			MAIL DATE 07/10/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/511,202

Applicant(s)

ALLNUTT ET AL.

Examiner

Janet L. Epps-Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 25-49 is/are rejected.
- 7) ☒ Claim(s) 9-24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-49 are presently pending for examination.

Claim Objections

2. Claims 9-24 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot serve as the basis for another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 9-24 have not been further treated on the merits.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-8, 27-34, and 38-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Masuda (US 4,808,417).

Instant claims 1-4, 7-8, 27-30, and 33-34 recite the following:

1. A method of animal feed production, comprising mixing at least one anaerobic bacterium with the feed.
2. The method of claim 1, wherein the feed is an aquaculture feed.
3. The method of claim 2, wherein the feed is a fish feed.
4. The method of claim 2, wherein the feed is a crustacean feed.
7. The method of claims 1-6, further comprising mixing at least one probiotic element with the feed.
8. The method of claims 1-6, wherein at least one anaerobic bacterium is viable at the time of production.
27. An animal feed comprising at least about 0.01% anaerobic bacterium.
28. The feed of claim 27, wherein the feed is an aquaculture feed.

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29. The feed of claim 28, wherein the feed is a fish feed.

30. The feed of claim 28, wherein the feed is a crustacean feed.

33. The feed of claim 27, wherein the feed further comprises one or more probiotic elements.

34. The feed of claim 27, wherein at least one anaerobic bacterium is viable at the time of production.

Claim 38 recites the feed of claim 27, wherein at least one anaerobic bacterium is a Clostridium, Fusobacterium, Peptostreptococcus, Bacteriodes, Butyrivibrio, Leptotrichia, Selenomonas, Succinimonas, Succinivibrio, Eubacterium, Lachnospira, Aracnia, Propionibacterium, Actinomyces, Bifidobacterium, Lactobacillus, Treponema, Borrelia, or Campylobacter, or a mixture of two or more of these. Claim 39 recites the feed of claim 27, wherein the anaerobic bacterium comprises at least one obligate anaerobe. Claim 40 recites the feed of claim 27, wherein the anaerobic bacterium comprises at least one facultative anaerobe.

Masuda describes a feed additive for fish cultivation which contains a combination comprising, as active components, a proteinase, a lipase, and a *viable mixture of three kinds of bacteria* (anticipates instant claim 8) consisting of lactic acid producing bacteria (LB), saccharificating bacteria (SB), and butyric acid producing bacteria (BB), wherein the bacteria are capable of coexisting in a symbiotic relationship and wherein the components of the combination are present in a proportion effective to improve the digestion and absorption by fish of fish feed supplemented therewith (This passage from Masuda anticipates claims 1-4 and 7). In one particular embodiment Masuda teaches the above feed additive, in which the lactic acid producing bacteria is *Streptococcus faecalis* (*facultative anaerobe*), the saccharificating bacteria is *Bacillus*

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mesentericus, and the butyric acid producing bacteria is *Clostridium butyricum* (*obligate anaerobe*) see columns 2-3 (this passage anticipates instant claim 38-40).

Additionally, other than the aforesaid effective components, Masuda also teaches that nutrition supplement materials such as a yeast, gluten meal, wheat flour, rice-bran oil cake, corn starch, potato starch, lactose, soybean cake and glucose are also effective and added at need. Especially, since yeast serves as a growth-promoting factor to viable bacteria, if added to the effective components, it makes it possible to maintain the viable microbial count constant (anticipates probiotic limitation; col. 3, lines 31-41).

Instant claims 5-6 and 31-32 recite:

5. The method of claim 1, wherein the feed is an agriculture feed.
6. The method of claim 5, wherein the feed is a chicken feed.
31. The feed of claim 27, wherein the feed is an agriculture feed.
32. The feed of claim 31 wherein the feed is a chicken feed.

Although Masuda does not specifically teach that the disclosed feed is useful as an agriculture feed or chicken feed, the feed of Masuda is considered to anticipate instant claims 5-6. The limitations of an "agriculture feed," and "a chicken feed," are considered intended use limitations. Absent evidence to the contrary, the recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

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The bacterium of Masada may also comprise spores, see for example wherein Masada discloses: "[T]he mixing ratio is preferably 1 to 8 parts of SB or BB against 1 part of LB. Incidentally, when SB and BB are used after forming spores, their properties such as heat resistance, dry resistance, and drug resistance are enhanced (anticipates claims 35-36).

5. Claims 1, 25, 27 and 35-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Zimmer (US Patent No. 5,501,857).

Claim 27 recites an animal feed comprising at least about 0.01% anaerobic bacterium, and claim 37 recites wherein at least one anaerobic bacterium is non-viable at the time of production. Claim 35 recites the feed of claim 27, wherein at least one anaerobic bacterium comprises a spore. Claim 36 recites the feed of claim 27, wherein at least one anaerobic bacterium is non-sporulated.

Zimmer discloses a dietary supplement to a food-producing animal, comprising a double capsule having an inner gelatin capsule and an outer gelatin capsule enclosing said inner gelatin capsule, said double capsule including a nutritional supplement therein, said double capsule further including viable gastrointestinal microorganisms therein, said nutritional supplement partitioned from said microorganisms; wherein said microorganisms are rendered non-viable when said nutritional supplement and said microorganisms are stored in a bolus or single capsule formulation; said microorganisms including one or more of *Lactobacillus acidophilus*, *Lactobacillus lactis*, *Lactobacillus casei*, *Streptococcus faecium*, *Pediococcus cerevisiae*, *Bifidobacterium*

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longum, live cell yeast *Saccharomyces cerevisiae*, *Aspergillus oryzae* or *Propionibacterium* (see claims of Zimmer). Additionally, Zimmer teaches:

"[d]elivery is achieved by feeding an animal a double capsule containing a first substance in a first capsule, which is enclosed with a second substance, in a second larger capsule. One of the two substances is a viable substance. The other substance is such that the viable substance is rendered nonviable when both substances are stored and administered simultaneously in a bolus or in a single capsule formulation. By "incompatible" is meant that one of the two substances prevents or inhibits the growth and/or affects the viability of the other substance. By viable is meant capability of life. The substance can come out of a dormant condition, such as a freeze-dried state to an active vegetative state. The viable substance is not completely in a spore state. The viable substance may be in a form that has **both spore** forming and **non-spore** forming components.

(See col. 5)

6. Zimmer anticipates the instant claims.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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8. Claims 1, 27, and 41-42, 44 are rejected under 35 U.S.C. 102(e) as being anticipated by Leer et al. (US Patent No. 6,506,389).

9. Claims 1, 27, and 41-42, and 44 are drawn to the feed of claim 27, wherein at least one anaerobic bacterium is recombinant, wherein the anaerobic bacterium comprises one or more bioactive compound; wherein the anaerobic bacterium comprises one or more recombinant protein or peptide.

10. Leer et al. discloses the following:

A composition comprising a component selected from the group of components comprising a protein or peptide as described herein an expression vector as described herein a recombinant microorganism as described herein or a part of said microorganism, said part expressing mucosa binding promoting activity a non pathogenic microorganism capable of expressing a protein or peptide as described herein or a part of said microorganism, said part expressing mucosa binding promoting activity as pharmaceutically active component and a pharmaceutically acceptable carrier in a pharmaceutically acceptable dosage form is covered by the invention. A composition comprising the abovementioned components in a form suitable for use as food additive is also envisaged to fall within the scope of the invention. The use of a component selected from the group of components comprising a protein or peptide as described herein an expression vector as described herein a recombinant microorganism as described herein or a part of said microorganism, said part expressing mucosa binding promoting activity a non pathogenic microorganism capable of expressing a protein or peptide as described herein or a part of said microorganism, said part expressing mucosa binding promoting activity as pharmaceutically active component in a pharmaceutical composition for prophylaxis and/or treatment of disease or illness associated with a mucosa colonizing pathogenic microorganism also falls within the scope of the invention.

As will be apparent from the above a method for improving food products comprising addition of a product as described herein and/or a non-pathogenic microorganism capable of expressing a protein or peptide as described herein or a part of said microorganism, said part expressing mucosa binding promoting activity to the food product forms an embodiment of the invention. Preferably such a method comprises addition of a product as described herein to the food product.

Obviously a food product comprising a product as described herein and/or a non-pathogenic microorganism capable of expressing a protein or peptide as described herein or a part of said microorganism, said part expressing mucosa binding promoting activity as additive is also covered. A food product comprising a product as described herein as additive is a particularly suitable embodiment. (see column 8, lines 1-41).

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11. Claim 27 and 41-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Sturino et al. (US Patent No. 6,686,192).

Claims 41-43 recite:

41. The feed of claim 27, wherein at least one anaerobic bacterium is recombinant.

42. The feed of claim 41, wherein the recombinant anaerobic bacterium comprises one or more bioactive compound.

43. The feed of claim 42, wherein the recombinant anaerobic bacterium comprises one or more antisense ribonucleic acid.

12. Sturino et al. teaches a method of fermenting milk comprising the addition of a culture of *Streptococcus thermophilus*, which harbors a recombinant DNA vector containing an oligonucleotide as which encodes an antisense ribonucleic acid to produce a fermentation media, and then fermenting said milk with said *Streptococcus thermophilus* cells to produce a fermentation product (see col. 20 of claims).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 46-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masuda, Zimmer or Leer et al. as applied to claim 27.

15. The teachings of Masuda, Zimmer, or Leer et al. as set forth above, is incorporated here. However, these references do not disclose wherein the anaerobic bacterium comprises from about 0.01% to 0.1%, 1% or 10% of the feed. Absent

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evidence of unexpected results, since the prior differs from the presently claimed invention only to the extent that it does not disclose the particular ranges of anaerobic bacterium, it would have been within the skill of the ordinary skilled artisan to vary the percentage of anaerobic bacteria in the animal feed of the prior art to identify the most optimal or workable ranges. See for example, MPEP § 2144.05, which states: “[G]enerally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Claim Rejections - 35 USC § 112

16. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

17. Claims 26 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 recites “[T]he method of claim 1, further comprising growing a biomass of *Photobacterium damsela* subsp, piscicida under anaerobic conditions, harvesting the biomass, rendering the *Photobacterium* nonviable, and drying the *Photobacterium*.” Claim 1 recites a method of animal feed production, comprising mixing at least one anaerobic bacterium with the feed. Claim 26 does not further limit the method of animal

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feed production recited in claim 1, claim 26 appears to be directed to a completely different method, namely, a method for producing a biomass.

Claim 45 recites: "[T]he feed of claim 44, wherein the recombinant anaerobic bacterium comprises a cecropin, penaeidin, bactenecin, callinectin, myticin, tachyplesin, clavanin, misgurin, pleurocindin, parasin, histone, acidic protein, or lysozyme." The scope of the instant claim is indefinite since it is not clear if proteins listed in claim 45 further limit the protein or peptide expressed in the recombinant anaerobic bacterium of claim 44, or if the proteins listed in claim 45 represent an entirely distinct set of proteins.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Ford/
Primary Examiner
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JLE